

## **REMARKS**

Claims 31, 34-37, 40-42, and 61-63 were pending in this application. Applicants have amended claims 31 and 37. Applicants submit that these amendments add no new matter.

### Interview Summary

Applicants would like to thank Examiner Yabut for her time and helpful comments during the telephonic interview of October 24, 2008. During the interview, the Nobles, Ginn, and Das references were discussed as were the amendments to claims 31 and 37 presented in this amendment. While the Examiner agreed that the amendments appear to overcome the rejection, she indicated that further consideration and searching would be required. Accordingly, no agreement was reached.

### Amendments to the Claims

Independent claim 31 is amended to recite withdrawing said second free end portion of said flexible member from said left atrial side prior to introducing an occlusion device for occluding said patent foramen ovale. Support for this amendment is found in the application as originally filed, for example, at paragraph 79.

Independent claim 37 is amended to recite withdrawing the at least one of said hexagonally shaped flexible member from the left atrial side prior to introducing an occlusion device for occluding said patent foramen ovale. Support for this amendment is found in the application as originally filed, for example, at paragraph 79.

Applicants submit that these amendments add no new matter.

### Claim Rejections under 35 U.S.C. § 103

#### ***Nobles and Ginn***

Claims 31, 34, 35, and 60-63 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent Application Publication No. 2002/0045908 to Nobles (“Nobles”) in view of U.S. Patent No. 6,702,835 to Ginn (“Ginn”). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 31 has been amended to recite that the second free end portion of the flexible member is withdrawn from the left atrial side prior to introducing an occlusion device for occluding the patent foramen ovale.

Nobles teaches a suturing device that allows a physician to remotely suture biological tissue (abstract). Nobles teaches that the device can be used to suture a patent foramen ovale (para. 141, 193). Nobles' device includes a housing that contains suture clasp arms 28, 30 (para. 142, FIG. 2). After Nobles' device is inserted through the patent foramen ovale, the suture clasp arms are deployed beyond the housing on the left-atrial side of the defect (paras. 142, 189, 190, 193; FIG. 35). Penetrating mechanisms or needles 136 are then introduced through the septal wall (paras. 143, 190; FIG. 36). Suture catches 38 on the penetrating mechanisms catch the sutures on the suture clasps (paras. 143, 190; FIG. 36). The suture catches and suture are then pulled proximally through the septal wall after which the housing containing the suture clasps is removed from the hole in the tissue (paras. 143, 190, 191, 193; FIG. 37).

The Examiner asserts that Nobles' suture 40 reads on Applicants' claimed occlusion device and that Nobles' suture clasp arms 28, 30 reads on Applicants' flexible member (Office action, pages 2-3). Applicants submit that Nobles fails to anticipate or obviate Applicants' claimed invention at least because Nobles' sutures are introduced through the septal wall prior to Nobles suture clasp arms being removed. Nobles neither teaches nor suggests that the suture clasp arms are removed from the left atrial side prior to introducing Nobles' suture through the septal wall. In contrast to the teachings of Nobles, Applicants' claimed invention requires that the second free end portion of the flexible member is withdrawn from the left atrial side of the patent foramen ovale prior to introducing an occlusion device.

Applicants submit that Ginn fails to remedy the deficiencies of Nobles. Ginn teaches an apparatus and methods for closing a septal defect. According to Ginn, a needle is advanced through a patient's vasculature into the heart until the needle is disposed adjacent the septum. The needle is then directed through the septum, creating a puncture, and passing through the septum until the needle is disposed in the opposite chamber on the other side of the septum. The needle is used to occlude the defect. (See abstract; col. 7, line 60 to col. 8, line 38; and FIGS. 5A-D).

Applicants submit that if Ginn's needle reads on Applicants claimed flexible member, Ginn fails to teach removing the needle prior to introducing an occlusion device. Conversely, if Ginn's needle reads on Applicants' claimed occlusion device, Ginn fails to teach that a flexible member is removed from the left atrial side prior to Ginn's introduction of the needle occlusion device. Accordingly, Applicants submit that Ginn fails to remedy the deficiencies of Nobles.

For all these reasons, Applicants respectfully request that the rejection of claim 31 over Nobles in view of Ginn under 35 U.S.C. § 103 be reconsidered and withdrawn. Applicants submit that rejected dependent claims 34, 35, and 60-63 are patentable at least for the same reasons that claim 31 is patentable and respectfully request that the rejection of these claims also be reconsidered and withdrawn.

***Nobles, Ginn, and Sawyer***

Claim 36 stands rejected under 35 U.S.C. § 103(a) over Nobles in view of Ginn, and U.S. Patent No. 5,749,895 to Sawyer ("Sawyer"). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 36 depends from claim 31. Accordingly, Applicants submit that claim 36 is patentable at least for the same reasons that claim 31 is patentable as discussed previously.

Further, Applicants submit that Sawyer fails to remedy the deficiencies of Nobles, and Ginn as applied to claim 31. In particular, Sawyer teaches methods for joining tissue by using a patch and a mechanical support (abstract; col. 2, lines 39-55). Sawyer neither teaches nor suggests a patent foramen ovale and therefore fails to teach introducing the second free end portion of the first flexible member through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through a septum primum. Accordingly, Applicants submit that claim 36 is patentable in view of Nobles, Ginn, and Sawyer.

For all these reasons, Applicants respectfully request that the rejection of claim 36 be reconsidered and withdrawn.

***Nobles, Ginn, and Das***

Claims 37 and 40-41 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Nobles in view of Ginn and further in view of U.S. Patent No. 5,334,217 to Das (“Das”). Applicants traverse the rejection to the extent it is maintained over the claim as amended.

Claim 37 has been amended to recite withdrawing the at least one hexagonally shaped flexible member from the left atrial side prior to introducing an occlusion device for occluding the patent foramen ovale.

The teachings of Nobles and Ginn have been discussed above.

Applicants submit that Das fails to remedy the deficiencies of Nobles and Ginn. Das teaches that a hexagonally shaped septal occluder can be introduced to occlude a septal defect (col. 10, lines 5-9; FIG. 5C; and FIG. 10). Das, however, does not teach removing the hexagonally shaped occlusion device from the patent foramen ovale.

Applicants submit that if Das’ hexagonally shaped septal occluder reads on Applicants claimed flexible member, Das fails to teach removing the hexagonally shaped septal occluder from the left atrial side of the patent foramen ovale prior to introducing an occlusion device. Alternatively, if Das’ hexagonally shaped septal occluder reads on Applicants’ claimed occlusion device, Das fails to teach that a flexible member is removed from the left atrial side prior to Das’ introduction of the hexagonally shaped septal occlusion device. Accordingly, Applicants submit that Das fails to remedy the deficiencies of Nobles.

For all these reasons, Applicants respectfully request that the rejection of claim 37 over Nobles in view of Ginn and further in view of Das under 35 U.S.C. § 103 be reconsidered and withdrawn. Further, Applicants submit that rejected dependent claims 40 and 41 are patentable at least for the same reasons that claim 37 is patentable and respectfully request that the rejection of these claims also be reconsidered and withdrawn.

***Nobles, Ginn, Das, and Sawyer***

Claim 42 stands rejected under 35 U.S.C. § 103(a) over Nobles in view of Ginn, Das, and Sawyer. Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 42 depends from claim 37. Accordingly, Applicants submit that claim 42 is patentable at least for the same reasons that claim 37 is patentable as discussed previously.

Further, Applicants submit that Sawyer fails to remedy the deficiencies of Nobles, Ginn and Das as applied to claim 37. In particular, Sawyer, as discussed previously, teaches methods for joining tissue by using a patch and a mechanical support (abstract; col. 2, lines 39-55). Sawyer neither teaches nor suggests a patent foramen ovale and therefore fails to teach withdrawing a hexagonally shaped flexible member prior to introducing an occlusion device for occluding a patent foramen ovale. Accordingly, Applicants submit that claim 42 is patentable in view of Nobles, Ginn, Das, and Sawyer.

For all these reasons, Applicants respectfully request that the rejection of claim 42 be reconsidered and withdrawn.

## **CONCLUSION**

Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request that the Examiner telephone the undersigned attorney to discuss any outstanding issues.

Respectfully submitted,

Date: January 20, 2009  
Limited Recognition No.: L0363

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BOS-1243758 v1

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